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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/495,823	01/31/2000	Maria Alexandra Glucksman	5800-79	5331

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ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
1652	15

DATE MAILED: 07/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/495,823	GLUKSMANN ET AL.
	Examiner	Art Unit
	Yong Pak	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 January 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 218 and 268 is/are pending in the application.
- 4a) Of the above claim(s) 250-253 and 256-268 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 243-249, 254 and 255 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7 and 15</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 243-268 are pending.

Election/Restrictions

Applicant's election without traverse of Group I (claims 243-249 and 254-255) in Paper No. 8 is acknowledged.

Claims 250-253 and 256-268 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

Specification

The specification is objected to because ATCC accession number is left blank, on page 11 for example.

Claim Objections

Claims 243-249 and 254-255 are objected for being drawn to non-elected products, SEQ ID NOs: 2, 4 and 6 and DNA encoding SEQ ID NO:1, 3 and 5.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 247-248 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. Claims 247-248 read on a product of nature, a naturally occurring cell or a composition comprising the cell (human). This rejection can be overcome by amending the claims as "A nonhuman mammalian ..", for example.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 243-249 and 254-255 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 243, 245-249 and 254-255 are drawn to allelic variants of nucleic acids sequence of SEQ ID NO:8. Therefore, these claims are drawn to a subgenus of allelic DNAs that encode polypeptides comprising SEQ ID NO:7. The specification discloses only one allele within the scope of the genus, SEQ ID NO:8. There is no description of how the structure of SEQ ID NO:8 relates to the structure of any strictly neutral alleles. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. Therefore, the specification fails to describe common attributes of the genus.

Claims 243-249 and 254-255 are drawn to DNA that is at least 45% identical to SEQ ID NO:8, DNA comprising a 15 nucleotides of SEQ ID NO:8, and DNA encoding a polypeptide comprising at least 12 contiguous amino acids of SEQ ID NO:7. A description of roughly half of the whole structure of SEQ ID NO:8 and only 50 nucleic acids or 16 amino acids, which represent less than 3% of the whole structure of SEQ ID NO:8, amount to insufficient description of the structure of the DNA molecule in this claim. Therefore, these claims are drawn to a large variable genus of DNA molecules encoding polypeptides having unknown activity or inactive variants with an insufficient limitation on structure. The specification only teaches DNA encoding the sulfatase structure of SEQ ID NO:7, derived from human. The specification does not describe the function of all the polypeptide sequences encoded by the DNA molecules derived or modified from SEQ ID NO:8 and therefore, many functionally unrelated polypeptides are encompassed within the scope of these claims. Therefore, the specification fails to describe representative species by any identifying characteristics or functionality other than being comprised of SEQ ID NO:8 or being derived from SEQ ID NO:8.

Given this lack of the description of the representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 243-249 and 254-255.

Claims 243-249 and 254-255 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA encoding the sulfatase of SEQ ID NO:7, does not reasonably provide enablement for DNA molecules encoding polypeptides not homologous to SEQ ID NO:8. The specification does not reasonably provide enablement for DNA molecules encoding polypeptides having unknown function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988).

They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims encompass molecules having very low structural similarity to SEQ ID NO:8 that exhibit sulfatase activity and proteins of unknown functionality. The structural limitations are as follows: 45% of the whole structure of SEQ ID NO:10-12 and only 15 nucleic acids or 12 amino acids, which represent 3% of the whole structure of SEQ ID NO:8. Despite knowledge in the art for isolating polynucleotides, the specification fails to provide guidance regarding which amino acids of SEQ ID NO:7 are required to impart a polypeptide as a sulfatase. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification, which places weak limitation on the structure of the polypeptides as discussed above, does not support the broad scope of the claims because the specification does not establish: (A) regions of the sulfatase structure which may be modified without effecting its activity; (B) the general tolerance of to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

In the state of the art, the function of a polypeptide is unpredictable from its structure and the functionality of a polypeptide must be known in order to use the polypeptide. Therefore, the specification does not teach how to use polypeptides with unknown function.

Therefore, one of ordinary skill would require guidance in order to make DNA encoding sulfatase with structures different from SEQ ID NO:11 and how to use DNA encoding polypeptides having unknown function in a manner reasonable correlated with

the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claims 243-249 and 254-255 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the plasmid of claims 243-249 and 254-255 are required to practice the claimed invention. As a required element it/they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it/they is/are not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the microorganism(s). See 37 C.F.R. § 1.802.

The specification does not provide a repeatable process for obtaining the microorganism(s) and it is not apparent if the microorganism(s) is/are readily available to the public. The specification must contain the date that the microorganism(s) was/were deposited, the name of the microorganism(s) and the address of where the microorganism(s) was/were deposited.

If the deposit(s) has/have not been made under the Budapest Treaty, then in order to certify that the deposit(s) meets the criteria set forth in 37 C.F.R. § 1.801-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registration number,

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showing that:(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;(c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;(d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807; and (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 243-249 and 254-255 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 243-249 and 254-255 are incomplete because the deposit number intended in the space following “Patent Deposit Numbers” is missing.

In claims 243, 245-249 and 254-255, the exact hybridization condition is unclear. Different nucleic acids hybridize to a DNA sequence under different conditions. Therefore, the scope of DNA molecules encompassed by claim 6 is unclear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 243-249 and 254-255 are rejected under 35 U.S.C. 102(b) as being anticipated by Peters et al.

Peters et al. (form PTO-892) teach a nucleic acid molecule which is at least 45% identical to SEQ ID NO:8 and a nucleic acid molecule comprising a fragment comprising at least 15 nucleotides of SEQ ID NO:8 of the instant invention (page 3376). Peters et al. also teach a vector comprising the DNA molecules, a host cell comprising said vector and a method of producing the polypeptides encoded by the DNA molecules (page 3375). Therefore, the teachings of Peters et al. anticipates claims 243-249 and 254-255.

Claims 243-249 and 254-255 are rejected under 35 U.S.C. 102(a) as being anticipated by Wood et al.

Wood et al. (form PTO-892) teach a nucleic acid molecule which is at least 45% identical to SEQ ID NO:8 of the instant invention, a nucleic acid molecule comprising a fragment comprising at least 15 nucleotides of SEQ ID NO:8 of the instant invention and a nucleic acid molecule encoding a polypeptide fragment comprising of at least 12 contiguous amino acids of SEQ ID NO:7 of the instant invention (page 42 and 287 and see Sequence Search Results). Wood et al. also teach a vector comprising the DNA

molecule, a host cell comprising said vector and a method of producing the polypeptides encoded by the DNA molecules (claims 5-11 on page 289). Therefore, the teachings of Wood et al. anticipates claims 243-249 and 254-255.

No claims are allowed.

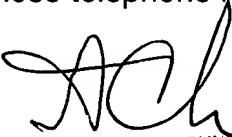
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

July 25, 2002



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600